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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,821

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EXAMINER

HUSON, MONICA ANNE

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/749,821	<b>Applicant(s)</b> BURGMEIER ET AL.	
	<b>Examiner</b> MONICA A. HUSON	<b>Art Unit</b> 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6,7,9-11,13,14,20-26,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6,7,9-11,13,14,20-26,29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

This office action is in response to the Remarks filed 26 November 2008.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-26, 29-30, 6-7, 9-11, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang, in view of Forte et al. (U.S. Patent Application Publication 2003/0054161).

Regarding Claim 20, Wang et al., hereafter "Wang," show that it is known to carry out method of forming a polymeric part for a medical device (Abstract) comprising passing a mass of molten polymer material composition through an opening to form an emitted mass (Column 2, lines 57-60), subsequently cooling the emitted mass, without substantially mixing the emitted mass material, whereby the cooled emitted mass comprises at least two regions of material located within the cooled mass in a fixed relationship to each other said fixed relationship corresponding substantially to the sequence of emission of the polymer material forming each said region (Figure 2; it is inherent that the extruded mass will be cooled prior to usage and shipping to consumers), wherein the method further comprises: varying an amount of crystallization modifier in the polymer composition passing through said opening between the emission of the material forming the first region and the emission of the material forming the second region, whereby at least one of the two regions is provided with a positive amount of said crystallization modifier and the two regions are provided with differing amounts of said crystallization modifier (crystallization modifier=boric acid; Column 6, lines 1-12; one section of the extruded article contains boric acid and another section

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does not). Wang does not show at least two regions of material located within the mass in a single layer along the length thereof. Forte et al., hereafter "Forte," shows that it is known to carry out a method of making an extruded polymeric article wherein the crystallization modifier can be present in any desired distribution or fashion, depending on the desired article (Para. 0013-0014, 0031, 0036, 0040-0041), also noting that the film can be a single extruded layer (Para. 0013, 0036). Therefore, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Forte's crystallization modifier distribution teachings during Wang's molding method in order to extrude the article having the desired crystallization modifiers at the desired locations.

Regarding Claim 21, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein the amount of the crystallization modifier is varied within the range of 0 to about 20 percent by weight of the composition (Column 5, lines 1-8), meeting applicant's claim.

Regarding Claim 22, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein the passing step comprises extruding said molten polymer composition through a die head (Column 5, lines 8-9), meeting applicant's claim.

Regarding Claim 23, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, but he does not show injection molding. Forte shows that it is known to carry out a method wherein an article is made using a polymer and a crystallization modifier wherein the molding material is injected into a mold form (Para. 0012). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Forte's injection molding as an alternative process to Wang's extrusion in order to form articles that are more suited to finite mold processes (i.e. articles that are not well suited to the continuous processing of extruding processes).

Regarding Claims 24-25, 29, 30, and 10, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, including showing the claimed balloon structure of Claim 30 (Figure 2), but he does not show the particular crystallization

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modifier presence as claimed. Forte shows that it is known to carry out a method of making an extruded polymeric article wherein the crystallization modifier can be present in any desired distribution or fashion, depending on the desired article (Para. 0013-0014, 0031, 0036, 0040-0041). Therefore, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Forte's crystallization modifier distribution teachings during Wang's molding method in order to extrude the article having the desired crystallization modifiers at the desired locations.

Regarding Claim 26, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein the crystallization modifier is a crystallization inhibitor (Column 2, lines 58-63; boric acid=crystallization modifier), meeting applicant's claim.

Regarding Claim 6, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein the polymer composition comprises polyesters (Column 3, lines 19-24; PBT is a polyester), meeting applicant's claim.

Regarding Claim 7, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein the emitted mass is a polymer tube and said polymer tube is subsequently formed into a dilatation balloon (Column 2, lines 43-53), meeting applicant's claim.

Regarding Claim 9, Wang shows the process as claimed as discussed in the rejection of Claim 7 above, including a method wherein the dilatation balloon has a balloon body portion and proximal and distal waist portions, the crystallization modifier is a crystallization inhibitor and the balloon is formed such that the crystallization modifier is present in the distal waist portion of the balloon (Column 2, lines 58-63; Column 6, lines 1-8), meeting applicant's claim.

Regarding Claim 11, Wang shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein said part is a discreetly formed portion of a balloon catheter outer shaft (Column 6, lines 1-18), meeting applicant's claim.

Regarding Claim 13, Wang shows the process as claimed as discussed in the rejection of Claim 11 above, including a method wherein said outer shaft comprises proximal and distal ends, the distal ends adapted for bonding to a proximal waist portion of a dilatation balloon, said regions are located along the length of the shaft and at least a region immediately proximal of said distal end is provided with a crystallization enhancer (Column 6, lines 1-8; Column 9, lines 48-58), meeting applicant's claim.

Regarding Claim 14, Wang shows the process as claimed as discussed in the rejection of Claim 13 above, including a method wherein the crystallization enhancer is not present in at least one region of the catheter outer shaft portion (Column 6, lines 5-8), meeting applicant's claim.

### ***Response to Arguments***

Applicant's arguments filed 26 November 2008 have been fully considered but they are not persuasive.

Applicant contends that Forte relates "neither to extruded polymer articles nor to medical devices". This is not persuasive because Forte clearly is related to extruded polymer articles as described in [0014] and [0036]. Forte was not cited as being related to medical devices; Wang shows this feature of the invention.

Applicant contends that "The Office Action fails to articulate a reason why one would combine the Wang et al. and Forte documents in fashioning a medical device part". This is not persuasive because reasons for combining were clearly stated in the last sentence of the first paragraph on page 3 of the Office Action. More specifically, Wang shows that it is known to fashion a medical device that contains a crystallization modifier. Wang does not show the claimed distribution. Forte shows that it is known to place crystallization modifiers at various locations, including the claimed "two regions located within the mass in a single layer along the length thereof" by Forte's disclosure that "The amount of hcPP contained *within each layer* may vary according to the properties desired in the film" (emphasis added). This disclosure immediately envisages a teaching that within a layer, the amounts of crystallization modifier can vary, clearly suggesting two regions within a single layer. It is maintained that one of

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ordinary skill in the art who considers the teachings of Wang, who uses a crystallization modifier but does not discuss intralayer distributions, would easily look to Forte for the intralayer placement options of the crystallization modifier.

Applicant contends that Forte's teachings do not suggest a crystallization modifier being present "in any desired distribution or fashion". This is not persuasive because Forte teaches that the modifier can be in various amounts, i.e. locations, within each layer "according to the properties desired in the film" ([0014]). This broad teaching can easily be interpreted to suggest nearly any possible distribution that is needed depending on what properties need to be present (and at what location) in the film. Forte establishes that it is known to vary the amount, i.e. location, of crystallization modifier within a layer based on the desired end result.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONICA A. HUSON whose telephone number is (571)272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Monica A Huson  
Primary Examiner  
Art Unit 1791

/Monica A Huson/

Primary Examiner, Art Unit 1791